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DEC 1 9 2003

510 (K) Summary of Safety and Effectiveness

Company Name:	Spinal Innovations, Inc. 7850 Stage Hills Blvd. Suite 105 Bartlett, TN 38133 (901) 373-8855 (901) 373-8303 fax
510(k) Contact:	Joe Clift Vive President of Regulatory Affairs (901) 373-8855
Trade Name:	Spinal Innovations REVOLUTION™ Spinal Fixation System
Common Name:	Hook, Rod and Screw Spinal Fixation System
Classification:	888.3050 Appliance, Fixation, Spinal Interlaminal – class II 888.3070 Orthosis, Spondylolisthesis Spinal Fixation – class II 888.3070 Orthosis, Spinal Pedicle Fixation – class II
Device Product Code:	87 KWP, MNH and MNI
Predicate Devices:	Silhouette™ Spinal System by Centerpulse Spine-Tech. CD Horizon Multi Axial Screw System and TSRH™ Spinal Implant System by Sofamor Danek, Inc MOSS™ Miami System by DePuy Motech, Inc. Ascend™ Spinal System with the Shadow™ Spinal System by Spinal Innovations, Inc.

Device Description

The Spinal Innovations REVOLUTION ™ Spinal Fixation System is a temporary implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar and sacral areas of the spine. Implants of this system consist of hooks and/or screws connected to rods and are intended to be removed after solid fusion has occurred. This system includes fixed and polyaxial screws of varying diameters and lengths, and hooks in varying designs and lengths, curved and straight rods and transverse connectors.

Intended Use

The Spinal Innovations REVOLUTION ™ Spinal Fixation System, when used as a pedicle screw fixation system, is indicated for use in patients: a) having severe spondylolisthesis (Grade 3 and 4) at the L5-S1 joint; b) who are receiving fusion using autogenous graft only; c) who are having the device fixed or attached to the lumbar or sacral spine; and d) who are having the device removed after the development of a solid fusion mass. When used for this indication, the fusion mass may not go above the L5-S1 joint, the levels of pedicle screw fixation may span from L3 to the sacrum.

The Spinal Innovations REVOLUTION ™ Spinal Fixation System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as a hook and sacral screw system (other than pedicle screw fixation system for high grade spondylolisthesis), the Spinal Innovations REVOLUTION ™ Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined by chronic back pain of discogenic origin with the degeneration of the disc confirmed by a history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal surgery/fusion. When used for this indication, screws of the Spinal Innovations REVOLUTION ™ Spinal Fixation System are intended for sacral/iliac attachment only. Hooks of the system are intended for posterior thoracic and/or lumbar use only. The levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

Testing

Biomechanical testing demonstrated that the components of the Spinal Innovations REVOLUTION ™ Spinal Fixation System exhibit equivalent mechanical performance compared to predicate devices. Testing included the following:

1) Interconnection testing of individual system components per ASTM F 1798-97. The tests included axial gripping capacity of polyaxial screws and polyaxial screw flexion/extension static and fatigue testing.

Testing results of the various system components show that the data compares directly to predicate device testing and meets or exceeds other predicate devices. Therefore, the results support that the REVOLUTION ™ Spinal Fixation System is substantially equivalent to the predicate devices.

Basis for Substantial Equivalence

The Spinal Innovations REVOLUTION ™ Spinal Fixation System is substantially equivalent in material, design and function to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2003

Mr. Joseph S. Clift
Vice President, Regulatory Affairs
Spinal Innovations, Inc.
7850 Stage Hill Boulevard, Suite 105
Bartlett, Tennessee 38133

Re: K032219
Trade Name: Spinal Innovations REVOLUTION™ Spinal Fixation System
Regulatory Number: 21 CFR 888.3070, 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNI, MNH, KWP
Dated: October 28, 2003
Received: November 28, 2003

Dear Mr. Clift:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number K032219

Device Name: Spinal Innovations REVOLUTION ™ Spinal Fixation System

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(510(k) Number) K032219